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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/801,089 | 03/08/2001 | David R. Phillips | MPI95-0151RCPA1DV1M | 7657 |

7590 08/31/2004

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC
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CAMBRIDGE, MA 02139

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/801,089 | PHILLIPS ET AL. |
| | Examiner | Art Unit |
| | G. R. Ewoldt, Ph.D. | 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 June 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-23 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-23 and 30-40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's amendments and remarks, filed 6/29/04, are acknowledged. In view of Applicant's amendments and remarks the previous rejections under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 103(a) have been withdrawn.

2. In view of the withdrawal of the previous art rejection, Claims 35-40 are rejoined. Claims 21-23 and 30-40 are being acted upon.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22-23 and 30-34 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons set forth in the action mailed 3/29/04. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the generic method comprising the steps of Claim 22 and the limitations of Claims 23 and 30-34.

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that, "Applicants have amended claim 22 to more closely align the steps with statements from the specification. As for the limitations of claims 23 and 30-34, Applicants follow with more precise information identifying some support for these claims".

Regarding Claim 22, it is noted that Applicant has again failed to cite actual support in the specification for the claimed method. Regarding the additional dependent claims, in each case Applicant has pointed to specific examples for support. As set forth previously, specific examples, are insufficient support for the generic method of the claims. For example, Applicant indicates that support for Claim 23 can be found at page 41, line 18, page 54, line 20, and page 57, lines 4-5. In

each these examples just a specific integrin β was assayed in a specific way. There is no generic disclosure of a method encompassing all of the integrin β 's of independent Claim 21 in a method of identifying signaling employing the generic method of Claim 22. Additionally, none of these examples disclose the additional limitations of the dependent claims in a generic context as claimed.

5. The following are new grounds for rejection necessitated by Applicant's amendment.

6. Claims 21-23 and 30-40 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, "a method to identify outside-in or inside-out signaling ... comprising the step of determining whether the cytoplasmic domain of said integrin is phosphorylated wherein a phosphorylated cytoplasmic domain indicates integrin-mediated outside-in or inside-out signaling".

Applicant indicates that support for this new limitation can be found at page 37, lines 15-17 and page 45, line 25, of the specification.

A review of the specification discloses that page 37 discloses only a method of determining whether tyrosine residues are phosphorylated, not the more generic method of the claims, and there is no disclosure of a method of determining outside-in or inside-out signaling. Page 45 discloses only a specific example encompassing the determination of kinases associated with GPIIIa in platelets and not the generic method of the instant claims. While outside-in and inside-out signaling are disclosed, said signalings are disclosed only in a context relating to *syk* tyrosine kinase and not the method of the instant claims.

7. No claim is allowed.

8. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

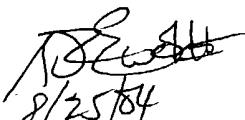
Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


8/25/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER